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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/673,400 | 12/27/2000 | Thomas Specht | SCH-1779 | 7219 |

7590 10/22/2002

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EXAMINER

KATCHEVES, KONSTANTINA T

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 10/22/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------------|---------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/673,400 | SPECHT ET AL. | |
| | Examiner | Art Unit | |
| | Konstantina Katcheves | 1636 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 01 August 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-38 is/are pending in the application.

4a) Of the above claim(s) 1-22 and 32-38 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 23-31 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 27 December 2000 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. _____.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 10.

4) Interview Summary (PTO-413) Paper No(s) _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

DETAILED ACTION

Claims 1-38 are pending in the present application.

Election/Restrictions

Applicant's election of Group III and SEQ ID NO:38 in Paper No. 12 is acknowledged.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Accordingly, claims 23-31 and SEQ ID NO:38 are currently under examination.

Claims 1-22 and 32-38 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in Paper No. 12.

Claim Objections

Claims 23-31 are objected to because these claims recite SEQ ID Nos for non-elected sequences. Appropriate correction is required.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 56 of the specification. Applicant is required to delete this and any other embedded hyperlinks and/or other form of browser-executable codes. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 25 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The written description requirement is established by 35 U.S.C. 112, first paragraph which states that the: “*specification* shall contain a written description of the invention. . .[emphasis added].” The written description requirement has been well established and characterized in the case law. A specification must convey to one of skill in the art that “as of the filing date sought, [the inventor] was in possession of the invention.” See *Vas Cath v. Mahurkar* 935 F.2d 1555, 1560 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). Applicant may show that he is in “possession” of the invention claimed by describing the invention with all of its claimed limitations “by such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” See *Lockwood v. American Airlines Inc.* 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Applicant’s claims are drawn to partial sequences of SEQ ID NO:38 that can bind to the polypeptide partial sequences. These are genus claims that encompass a wide array of molecules. The specification does not disclose any of the variants or modifications, nor does it provide any teachings as to how the structures of these sequences relate to their function. The

specification does not describe the complete structure of the sequence in such a way that one of skill in the art would reasonably conclude that Applicant was in possession of the invention. Since these claims are drawn to a polypeptide, it is well-known in the art that a single residue change or deletion could eliminate or change the function of the polypeptide. To overcome this problem Applicant should provide information relating the structure of the sequences such as motifs, domains or consensus sequence that relate to a specific function to support claims to such a broad genus. In other words, Applicant has failed to describe the invention in terms of partial structure and relevant identifying characteristics. Absent such teachings and guidance as to the structure-function relationship of these molecules, the specification does not describe the claimed polypeptides in such full, clear, concise and exact terms such that Applicant had possession of these molecules at the time of filing of the present application.

Claims 23, 24 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the full length sequence of SEQ ID NO:38, does not reasonably provide enablement for partial sequences or sequences having 80% or 90% homology to SEQ ID NO:38. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to

consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art
- 7) the predictability of the art, and
- 8) the breadth of the claims.

Although all the factors above have been considered only those most relevant to the invention of the instant claims have been discussed. The invention of the instant claims is broadly drawn to partial sequences of SEQ ID NO:38 and sequences with 80% or 90% homology to partial sequences of SEQ ID NO:38. For the purposes of brevity, the sequences having homology and the partial sequences are hereinafter referred to as "partial sequences." The nature of the invention requires that one of skill in the art have knowledge regarding what common structural characteristics or motifs are required for all the sequences claimed. This information is necessary to make functional sequences partial sequences. Without such information, one of skill in the art would not reasonably know how to make the sequences claimed. The present claims read on an innumerable number of additions, deletions and mutations such that one of skill in the art would not be able to make the present invention. Moreover, one of skill in the art would be unable to use the partial sequences claimed given that

the specification does not disclose a function for the partial sequences of SEQ ID NO:38. Thus, it would be unpredictable to make or use the partial sequences of the present claims. Therefore given the breadth of the claims, the nature of the invention and the unpredictability of the art, Applicant is not in possession of the full scope of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-31 provide for the use of a nucleic acid sequence, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 27-31 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 23-26 are rejected under 35 U.S.C. 102(b) as being anticipated by Accession Number Q00833. (Mol. Gen Genet. Vol.249 1995).

The invention of the instant claims is broadly drawn to partial sequences of SEQ ID NO:38 and sequences with 80% or 90% homology to partial sequences of SEQ ID NO:38. Applicants claims are drawn to a partial sequences which includes any fragment of SEQ ID NO:38.

Accession Number Q00833 discloses amino acid sequences corresponding to amino acids of SEQ ID NO:38.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konstantina Katcheves whose telephone number is (703) 305-1999. The examiner can normally be reached on Monday through Friday 7:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-3388.

Konstantina Katcheves
October 21, 2002



TERRY MCKELVEY
PRIMARY EXAMINER